**VERCRIT**

**Case verification criteria [INV1115]**

This calculated data element uses laboratory and clinical results to determine the verification status of a TB case. The following algorithm is intended to assist programmers in assigning the case verification (VERCRIT) in surveillance systems designed to report TB cases.

**CASE VERIFICATION CRITERIA (“VERCRIT”) DEFINITION**

The assignment of case verification (Vercrit) follows the criteria below in hierarchical order:

* Not a Verified Case – Based on Stop Reason
* Positive culture
* Positive nucleic acid amplification (NAA) test
* Positive for acid-fast bacilli by microscopy (e.g., sputum smear, cytology or pathology of tissue specimen)
* Clinical case confirmation
* Provider diagnosis or Not a Verified Case – Based on State Decision

**NOTE:** *A record that satisfies the criteria for more than one case verification method will be classified in the verification level that appears first in the hierarchy. For example, a record that meets the criteria for both positive culture and clinical case definition will be classified as being verified by positive culture.*

**Case Verification Category [INV1115]** is assigned as follows:

### 0 ‑ Not a Verified Case {PHC162}

When the Reason Therapy Stopped or Never Started is Not TB.

* Reason Therapy Stopped or Never Started [INV1140] = Not TB {PHC72}

### 1 ‑ Positive Culture {PHC97}

When ANY Culture is Positive.

* Test type [INV290] = Culture {50941-4} **AND**

Test Result [INV291] = Positive {10828004}

### 1A - Positive NAA {PHC653}

 When ANY **Nucleic Acid Amplification Test** isPositive.

* Test type [INV290] = NAA {LAB673} **AND**

Test Result [INV291] = Positive {10828004}

### 2 ‑ Positive Smear/Tissue {PHC98}

 When:

ANY Smear, Cytology or Pathology is Positive

 -and-

ALL Cultures are either Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

 -AND-

**ALL Nucleic Acid Amplification Test Results** are either Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

|  |
| --- |
| * Test type [INV290] = Smear {20431-3} **AND**

Test Result [INV291] = Positive {10828004}**OR*** Test type [INV290] = Cytology {10525-4} **AND**

Test Result [INV291] = Positive {10828004}**OR*** Test type [INV290] = Pathology {50595-8} **AND**

Test Result [INV291] = Positive {10828004}**OR*** Test type [INV290] = Pathology/Cytology {LAB719} **AND**

Test Result [INV291] = Positive {10828004} |
| **AND** |
| * Test type [INV290] = Culture {50941-4} **AND**

Test Result [INV291] is one of the following:Not Done {385660001} **OR** Unknown {UNK} **OR**Indeterminate {82334004} **OR**Refused {443390004} **OR** Not Offered {410530007} **OR** Test Done Result Unknown {PHC2092} |
| **AND** |
| * Test type [INV290] = NAA {LAB673} **AND**

Test Result [INV291] is one of the following:Not Done {385660001} **OR** Unknown {UNK} **OR**Indeterminate {82334004} **OR**Refused {443390004} **OR**Not Offered {410530007} **OR** Test Done Result Unknown {PHC2092} |

### 3 ‑ Clinical Case Definition {PHC654}

 ***When Disease is Pulmonary Only:***

Site of TB Disease contains one or more of the following: Pulmonary, Pleural, or Lymphatic: Intrathoracic

-and-

ALL Cultures are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

**ALL Nucleic Acid Amplification** Test Results are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

ANY Chest Imaging Study is Consistent with TB,

-and-

ANY Tuberculin (Mantoux) Skin Test at Diagnosis or ANY Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis is Positive

-and-

Initial Drug Regimen has at least two drugs marked Yes

 **OR**

 ***When Disease is Extrapulmonary or Both Pulmonary and Extrapulmonary:***

**Site of TB Disease** contains one of the following: Adrenal; All teeth, gums and supporting structures; Anal; Appendix; Blood; Blood vessel; Bone and joint; Bone marrow; Brain; Breast; Cardiac valve; Colon; Duodenal; Epiglottis and larynx; Esophageal; Extrahepatic duct; Eye and ear appendages; Fetus and embryo; Gallbladder; Heart; Jejunum and ileum; Lip; Liver; Lymphatic Other; Lymphatic Unknown; Meninges; Middle ear and mastoid cells; Mouth region; Nasal; Nasopharyngeal; Other; Pancreatic; Paranasal sinus part; Pericardial; Peritoneal cavity; Pharyngeal; Pituitary; Placenta, umbilical cord and implantation site; Rectum; Salivary gland; Skin; Spinal cord; Splenic; Stomach; Genitourinary system; Lymphatic system of axilla; Lymphatic system of neck; Nervous system; Subcutaneous tissue; Thymus gland; Thyroid and/or parathyroid; Tongue; Tonsil and adenoid; Tracheal

-and-

ALL Cultures are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

**ALL Nucleic Acid Amplification** Test Results are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

ANY Tuberculin (Mantoux) Skin Test at Diagnosis or ANY Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis is Positive

-and-

Initial Drug Regimen has at least two drugs marked Yes

***When Disease is Pulmonary Only:***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| * **Site of TB Disease** [INV1133] (Select All That Apply) must contain one of the following:

|  |  |
| --- | --- |
| Intrathoracic lymphatic structure | {281778006} |
| Lung structure (Pulmonary) | {39607008} |
| Pleural structure | {3120008} |

 |
| **AND** |
| * For every test type [INV290] = Culture {50941-4}

Test Result [INV291] is one of the following:Negative {260385009} **OR**Not Done {385660001} **OR** Unknown {UNK} **OR**Indeterminate {82334004} **OR**Refused {443390004} **OR**Not Offered {410530007} **OR** Test Done Result Unknown {PHC2092}  |
| **AND** |
| * For every test type [INV290] = NAA {LAB673}

Test Result [INV291] is one of the following:Negative {260385009} **OR**Not Done {385660001} **OR** Unknown {UNK} **OR**Indeterminate {82334004} **OR**Refused {443390004} **OR**Not Offered {410530007} **OR** Test Done Result Unknown {PHC2092} |
| **AND** |
| For any chest imaging study type [LAB677] **AND** Study Result [LAB679] = Consistent with TB {PHC1873} |
| **AND** |
| * Test type [INV290] = Tuberculin Skin Test {TB119} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = IGRA-QFT {LAB671} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = IGRA-TSpot {LAB672} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = Other IGRA test {LAB720} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = IGRA-Unknown {71773-6} **AND**

Test Result [INV291] = Positive {10828004} |
| **AND – At least 2 of the following** |
| * Drug Name [INV1143] = Amikacin {641}

Used? [INV1144] = Yes {Y}   **OR*** Drug Name [INV1143] = Para-Aminosalicylicacid {7833}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Bedaquiline {1364504}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Capreomycin {78903}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ciprofloxacin {2551}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Clofazimine {2592}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Cycloserine {3007}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Delamanid {PHC1889}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ethambutol {4110}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ethionamide {4127}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Isoniazid {6038}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Kanamycin {6099}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Levofloxacin {82122}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Linezolid {190376}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Moxifloxacin {139462}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ofloxacin {7623}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Other (specify) {OTH}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Other Quinolones {PHC1888}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Pyrazinamide {8987}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Rifampin {9384}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Rifapentine {35617}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Streptomycin {10109}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Pretomanid {2198359}

Used? [INV1144] = Yes {Y} |

**OR**

 ***When Disease is Extrapulmonary only or Both Pulmonary and Extrapulmonary:***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * **Site of TB Disease** [INV1133] (Select All That Apply) must contain one of the following:

|  |  |
| --- | --- |
| Adrenal structure | {23451007} |
| All teeth, gums and supporting structures | {362102006} |
| Anal structure | {53505006} |
| Appendix structure | {66754008} |
| Blood | {87612001} |
| Blood vessel structure | {59820001} |
| Bone and joint, CS | {110522009} |
| Bone marrow structure | {14016003} |
| Brain structure | {12738006} |
| Breast structure | {76752008} |
| Cardiac valve structure | {17401000} |
| Colon structure | {71854001} |
| Duodenal structure | {38848004} |
| Epiglottis and larynx, CS | {110547006} |
| Esophageal structure | {32849002} |
| Extrahepatic duct structure | {16014003} |
| Eye and ear appendages | {PHC4} |
| Fetus and embryo | {C0230999} |
| Gallbladder structure | {28231008} |
| Heart structure | {80891009} |
| Jejunum and ileum, CS | {110611003} |
| Lip structure | {48477009} |
| Liver structure | {10200004} |
| Lymphatic Other | {PHC2} |
| Lymphatic Unknown | {PHC3} |
| Meninges structure | {1231004} |
| Middle ear and mastoid cells | {110708006} |
| Mouth region structure | {123851003} |
| Nasal structure | {45206002} |
| Nasopharyngeal structure | {71836000} |
| Other | {OTH} |
| Pancreatic structure | {15776009} |
| Paranasal sinus part | {120228005} |
| Pericardial structure | {76848001} |
| Peritoneal cavity structure | {83670000} |
| Pharyngeal structure | {54066008} |
| Pituitary structure | {56329008} |
| Placenta, umbilical cord and implantation site, CS | {110973009} |
| Rectum structure | {34402009} |
| Salivary gland structure | {385294005} |
| Skin structure | {39937001} |
| Spinal cord structure | {2748008} |
| Splenic structure | {78961009} |
| Stomach structure | {69695003} |
| Structure of genitourinary system | {21514008} |
| Structure of lymphatic system of axilla | {281777001} |
| Structure of lymphatic system of neck | {69831007} |
| Structure of nervous system | {25087005} |
| Subcutaneous tissue structure | {71966008} |
| Thymus gland structure | {9875009} |
| Thyroid and/or parathyroid structures | {297261005} |
| Tongue structure | {21974007} |
| Tonsil and adenoid structure | {303337002} |
| Tracheal structure | {44567001} |

 |
| **AND** |
| * For every test type [INV290] = Culture {50941-4}

Test Result [INV291] is one of the following:Negative {260385009} **OR**Not Done {385660001} **OR** Unknown {UNK} **OR**Indeterminate {82334004} **OR**Refused {443390004} **OR**Not Offered {410530007} **OR** Test Done Result Unknown {PHC2092} |
| **AND** |
| * For every test type [INV290] = NAA {LAB673}

Test Result [INV291] is one of the following:Negative {260385009} **OR**Not Done {385660001} **OR** Unknown {UNK} **OR**Indeterminate {82334004} **OR**Refused {443390004} **OR**Not Offered {410530007} **OR** Test Done Result Unknown {PHC2092} |
| **AND** |
| * Test type [INV290] = Tuberculin Skin Test {TB119} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = IGRA-QFT {LAB671} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = IGRA -TSpot {LAB672} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = Other IGRA test {LAB720} **AND**

Test Result [INV291] = Positive {10828004}  **OR*** Test type [INV290] = IGRA-Unknown {71773-6} **AND**

Test Result [INV291] = Positive {10828004} |
| **AND – At least 2 of the following** |
| * Drug Name [INV1143] = Amikacin {641}

Used? [INV1144] = Yes {Y}   **OR*** Drug Name [INV1143] = Para-Aminosalicylicacid {7833}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Bedaquiline {1364504}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Capreomycin {78903}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ciprofloxacin {2551}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Clofazimine {2592}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Cycloserine {3007}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Delamanid {PHC1889}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ethambutol {4110}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ethionamide {4127}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Isoniazid {6038}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Kanamycin {6099}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Levofloxacin {82122}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Linezolid {190376}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Moxifloxacin {139462}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Ofloxacin {7623}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Other (specify) {OTH}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Other Quinolones {PHC1888}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Pyrazinamide {8987}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Rifampin {9384}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Rifapentine {35617}

Used? [INV1144] = Yes {Y}  **OR*** Drug Name [INV1143] = Streptomycin {10109}

Used? [INV1144] = Yes {Y}**OR*** Drug Name [INV1143] = Pretomanid {2198359}

Used? [INV1144] = Yes {Y} |

### 5 – Suspected[[1]](#footnote-1) {415684004}

When none of the above criteria are met and the case is ***not*** overwritten as either 4-Verified by Provider Diagnosisor 0-Not a Verified Case.

### 4 ‑ Verified by Provider Diagnosis (Overwrites Suspected) {PHC165}

When the Suspected criteria case is overwritten as 4-Verified by Provider Diagnosis.

### 0 ‑ Not a Verified Case (Overwrites Suspected) {PHC162}

When the Suspected criteria case is overwritten as 0-Not a Verified Case.

**VERCRIT CASE EXAMPLES**

This section will provide an example for each case verification criteria.

### 0 ‑ Not a Verified Case {PHC162}

When the Reason Therapy Stopped or Never Started is Not TB.



### 1 ‑ Positive Culture {PHC97}

When the Sputum Culture or Culture of Tissue and Other Body Fluids is Positive.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TestType[INV290] | SpecimenSource Site[31208-2] | Date Collected/Placed[68963-8] | Date Reported/Read[82773-3] | Test Result (Qual.)[INV291] |
| TSTTB119 | Skin Structure39937001 | 01/01/2019 | 01/03/2019 | Positive10828004 |
| IGRA-QFT LAB671 | Blood87612001 | 01/04/2019 | 01/06/2019 | Indeterminate82334004 |
| Culture50941-4 | **Sputum****119334006** | **01/15/2019** | **02/12/2019** | **Positive****10828004** |
| Culture50941-4 | Blood87612001 | 05/09/2019 | 05/31/2019 | Positive10828004 |
| Smear20431-3 | Sputum119334006 | 01/04/2019 | 01/06/2019 | Positive10828004 |
| Smear20431-3 | Adrenal23451007 | 02/05/2019 | 02/07/2019 | Positive10828004 |
| Smear20431-3 | Sputum119334006 | 05/09/2019 | 05/13/2019 | Negative260385009 |
| Culture50941-4 | Sputum119334006 | 03/15/2019 | 03/30/2019 | Positive10828004 |

When there are multiple laboratory results for culture, the first Positive result will be identified as the lab determining the Case Verification Criteria.

### 1A - Positive NAA {PHC653}

 When the **Nucleic Acid Amplification Test** isPositive.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TestType[INV290] | SpecimenSource Site[31208-2] | Date Collected/Placed[68963-8] | Date Reported/Read[82773-3] | Test Result (Qual.)[INV291] |
| TSTTB119 | Skin Structure39937001 | 01/01/2019 | 01/03/2019 | Positive10828004 |
| IGRA-QFT LAB671 | Blood87612001 | 01/04/2019 | 01/06/2019 | Indeterminate82334004 |
| Culture50941-4 | Sputum119334006 | 01/15/2019 | 03/12/2019 | Negative260385009 |
| Smear20431-3 | Sputum119334006 | 01/04/2019 | 01/06/2019 | Negative260385009 |
| NAALAB673 | **Sputum****119334006** | **01/15/2019** | **01/17/2019** | **Positive****10828004** |
| NAALAB673 | Sputum119334006 | 03/21/2019 | 03/24/2019 | Positive10828004 |

When there are multiple laboratory results for NAA, the first Positive result will be identified as the lab determining the Case Verification Criteria.

### 2 ‑ Positive Smear/Tissue {PHC98}

 When:

Sputum Smear or Cytology or Pathology is Positive

 -and-

ALL Cultures are either Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

 -AND-

**ALL Nucleic Acid Amplification Test Results** are either Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TestType[INV290] | SpecimenSource Site[31208-2] | Date Collected/Placed[68963-8] | Date Reported/Read[82773-3] | Test Result (Qual.)[INV291] |
| TSTTB119 | Skin Structure39937001 | 01/01/2019 | 01/03/2019 | Positive10828004 |
| IGRA-QFT LAB671 | Blood87612001 | 01/04/2019 | 01/06/2019 | Indeterminate82334004 |
| Smear20431-3 | Sputum119334006 | 01/04/2019 | 01/06/2019 | Positive10828004 |
| Cytology10525-4 | **Bone Marrow****14016003** | **01/04/2019** | **01/05/2019** | **Positive****10828004** |
| Pathology50595-8 | Liver10200004 | 01/05/2019 | 01/10/2019 | Positive10828004 |
| Culture50941-4 |  |  |  | **Not Done****385660001** |
| NAALAB673 | **Sputum****119334006** | **03/21/2019** |  | **Unknown****UNK** |
| NAALAB673 | **Sputum****119334006** | **03/20/2019** | **03/22/2019** | **Indeterminate****82334004** |

When there are multiple laboratory results for Smears, Cytologies, or Pathologies, the first Positive result will be identified as the lab determining the Case Verification Criteria. When examining the cultures and NAA results, all test results must be examined.

### 3 ‑ Clinical Case Definition {PHC654}

***When Disease is Pulmonary Only:***

Site of TB Disease contains one or more of the following: Pulmonary, Pleural, or Lymphatic: Intrathoracic

-and-

ALL Cultures are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

**ALL Nucleic Acid Amplification** Test Results are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

ANY Chest Imaging Study is Consistent with TB,

-and-

ANY Tuberculin (Mantoux) Skin Test at Diagnosis or ANY Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis is Positive

-and-

Initial Drug Regimen has at least two drugs marked Yes

 **OR**

 ***When Disease is Extrapulmonary or Both Pulmonary and Extrapulmonary:***

**Site of TB Disease** contains one of the following: Adrenal; All teeth, gums and supporting structures; Anal; Appendix; Blood; Blood vessel; Bone and joint; Bone marrow; Brain; Breast; Cardiac valve; Colon; Duodenal; Epiglottis and larynx; Esophageal; Extrahepatic duct; Eye and ear appendages; Fetus and embryo; Gallbladder; Heart; Jejunum and ileum; Lip; Liver; Lymphatic Other; Lymphatic Unknown; Meninges; Middle ear and mastoid cells; Mouth region; Nasal; Nasopharyngeal; Other; Pancreatic; Paranasal sinus part; Pericardial; Peritoneal cavity; Pharyngeal; Pituitary; Placenta, umbilical cord and implantation site; Rectum; Salivary gland; Skin; Spinal cord; Splenic; Stomach; Genitourinary system; Lymphatic system of axilla; Lymphatic system of neck; Nervous system; Subcutaneous tissue; Thymus gland; Thyroid and/or parathyroid; Tongue; Tonsil and adenoid; Tracheal

-and-

ALL Cultures are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

**ALL Nucleic Acid Amplification** Test Results are either Negative, Not Done, Unknown, Indeterminate, Refused, Not Offered or Test Done Result Unknown

-and-

ANY Tuberculin (Mantoux) Skin Test at Diagnosis or ANY Interferon Gamma Release Assay for *Mycobacterium tuberculosis* at Diagnosis is Positive

-and-

Initial Drug Regimen has at least two drugs marked Yes

**Site of TB Disease**



**Tuberculin Skin Test and All Non-DST TB Laboratory Test Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TestType[INV290] | SpecimenSource Site[31208-2] | Date Collected/Placed[68963-8] | Date Reported/Read[82773-3] | Test Result (Qual.)[INV291] |
| TSTTB119 | **Skin Structure****39937001** | **01/01/2019** | **01/03/2019** | **Positive****10828004** |
| IGRA-QFT LAB671 | Blood87612001 | 01/04/2019 | 01/06/2019 | Indeterminate82334004 |
| Smear20431-3 | Sputum119334006 | 01/04/2019 | 01/06/2019 | Positive10828004 |
| Culture50941-4 | **Sputum****119334006** | **01/04/2019** | **02/18/2019** | **Negative****260385009** |
| NAALAB673 | **Sputum****119334006** | **03/21/2019** |  | **Unknown****UNK** |
| NAALAB673 | **Sputum****119334006** | **03/20/2019** | **03/22/2019** | **Indeterminate****82334004** |

**Chest Radiograph or Other Chest Imaging Study Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Type[LAB677] | Date of Study[LAB681] | Result[LAB678] | Cavity?[LAB679] | Miliary?[LAB680] |
| Plain Chest X-Ray | 01/04/2019 | Unknown [UNK] |  |  |
| CT Scan | **01/04/2019** | **Consistent with TB [PHC1873]** | **N** | **N** |

**Initial Drug Regimen**

|  |  |
| --- | --- |
| Drug Name [INV1143] | Used? [INV1144](Yes/No/Unknown) |
| Isoniazid | **Y** |
| Rifampin | **Y** |
| Pyrazinamide | **Y** |
| Ethambutol | **Y** |
| Streptomycin | **N** |
| Rifabutin | **N** |
| Rifapentine | **N** |
| Ethionamide | **N** |
| Amikacin | **N** |
| Kanamycin | **N** |
| Capreomycin | **N** |
| Ciprofloxacin | **N** |
| Levofloxacin | **N** |
| Ofloxacin | **N** |
| Moxifloxacin | **N** |
| Cycloserine | **N** |
| Para-Amino Salicylic Acid | **N** |
| Linezolid | **N** |
| Bedaquiline | **N** |
| Delaminid | **N** |
| Clofazimine | **N** |
| Pretomanid | **N** |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_ | **N** |

When there are multiple laboratory results for TSTs or IGRAs, the first Positive result will be identified as the lab determining the Case Verification Criteria. When there are multiple Chest Studies, the first Consistent with TB result will be identified as the lab determining the Case Verification Criteria. When examining the cultures and NAA results, all test results must be examined. When examining the Initial Drug Regimen at least two drugs must be marked as a Yes. When examining the Site of Disease at least one site should be provided, and that site must not be Site Not Stated.

### 5 – Suspected {415684004}

When none of the above criteria are met and the case is ***not*** overwritten as either 4-Verified by Provider Diagnosisor 0-Not a Verified Case.

**Site of TB Disease**



**Tuberculin Skin Test and All Non-DST TB Laboratory Test Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TestType[INV290] | SpecimenSource Site[31208-2] | Date Collected/Placed[68963-8] | Date Reported/Read[82773-3] | Test Result (Qual.)[INV291] |
| *TST**TB119* |  |  |  | *Not Done**385660001* |
| *IGRA-QFT LAB671* |  |  |  | *Not Done**385660001* |
| Smear20431-3 | Sputum119334006 | 01/04/2019 | 01/06/2019 | Positive10828004 |
| Culture50941-4 | **Sputum****119334006** | **01/04/2019** | **02/18/2019** | **Negative****260385009** |
| NAALAB673 | **Sputum****119334006** | **03/21/2019** |  | **Unknown****UNK** |
| NAALAB673 | **Sputum****119334006** | **03/20/2019** | **03/22/2019** | **Indeterminate****82334004** |

**Chest Radiograph or Other Chest Imaging Study Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Type[LAB677] | Date of Study[LAB681] | Result[LAB678] | Cavity?[LAB679] | Miliary?[LAB680] |
| Plain Chest X-Ray | 01/04/2019 | Unknown [UNK] |  |  |
| CT Scan | **01/04/2019** | **Consistent with TB [PHC1873]** | **N** | **N** |

**Initial Drug Regimen**

|  |  |
| --- | --- |
| Drug Name [INV1143] | Used? [INV1144](Yes/No/Unknown) |
| Isoniazid | **Y** |
| Rifampin | **Y** |
| Pyrazinamide | **Y** |
| Ethambutol | **Y** |
| Streptomycin | **N** |
| Rifabutin | **N** |
| Rifapentine | **N** |
| Ethionamide | **N** |
| Amikacin | **N** |
| Kanamycin | **N** |
| Capreomycin | **N** |
| Ciprofloxacin | **N** |
| Levofloxacin | **N** |
| Ofloxacin | **N** |
| Moxifloxacin | **N** |
| Cycloserine | **N** |
| Para-Amino Salicylic Acid | **N** |
| Linezolid | **N** |
| Bedaquiline | **N** |
| Delaminid | **N** |
| Clofazimine | **N** |
| Pretomanid | **N** |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **N** |



In the above example there is not a Positive TST or IGRA so this case will fall through the criteria to 5- Suspected and since the **Case Verification Category [INV1115]** provided by the State is not 4-Verified by Provider Diagnosis or 0-Not a Verified Case it will remain at the 5-Suspected category.

### 4 ‑ Verified by Provider Diagnosis (Overwrites Suspected) {PHC165}

When the Suspected criteria case is overwritten as 4-Verified by Provider Diagnosis.

**Site of TB Disease**



**Tuberculin Skin Test and All Non-DST TB Laboratory Test Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TestType[INV290] | SpecimenSource Site[31208-2] | Date Collected/Placed[68963-8] | Date Reported/Read[82773-3] | Test Result (Qual.)[INV291] |
| TSTTB119 | **Skin Structure****39937001** | **01/01/2019** | **01/03/2019** | **Positive****10828004** |
| IGRA-QFT LAB671 | Blood87612001 | 01/04/2019 | 01/06/2019 | Indeterminate82334004 |
| Smear20431-3 | Sputum119334006 | 01/04/2019 | 01/06/2019 | Positive10828004 |
| Culture50941-4 | **Sputum****119334006** | **01/04/2019** | **02/20/2019** | **Negative****260385009** |
| NAALAB673 | **Sputum****119334006612001** | **03/21/2019** |  | **Unknown****UNK** |
| NAALAB673 | **Sputum****119334006** | **03/20/2019** | **03/22/2019** | **Indeterminate****82334004** |

**Chest Radiograph or Other Chest Imaging Study Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Type[LAB677] | Date of Study[LAB681] | Result[LAB678] | Cavity?[LAB679] | Miliary?[LAB680] |
| Plain Chest X-Ray | 01/04/2019 | Unknown [UNK] |  |  |
| CT Scan |  | Not Done[385660001] |  |  |

**Initial Drug Regimen**

|  |  |
| --- | --- |
| Drug Name [INV1143] | Used? [INV1144](Yes/No/Unknown) |
| Isoniazid | **Y** |
| Rifampin | **Y** |
| Pyrazinamide | **Y** |
| Ethambutol | **Y** |
| Streptomycin | **N** |
| Rifabutin | **N** |
| Rifapentine | **N** |
| Ethionamide | **N** |
| Amikacin | **N** |
| Kanamycin | **N** |
| Capreomycin | **N** |
| Ciprofloxacin | **N** |
| Levofloxacin | **N** |
| Ofloxacin | **N** |
| Moxifloxacin | **N** |
| Cycloserine | **N** |
| Para-Amino Salicylic Acid | **N** |
| Linezolid | **N** |
| Bedaquiline | **N** |
| Delaminid | **N** |
| Clofazimine | **N** |
| Pretomanid | **N** |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **N** |

’

In the above example there is not a Consistent with TB results for any Chest Study so this case will fall through the criteria to 5- Suspected but since the **Case Verification Category [INV1115]** provided by the State is 4-Verified by Provider Diagnosis it will be set to the 4-Verified by Provider Diagnosis category.

### 0 ‑ Not a Verified Case (Overwrites Suspected) {PHC162}

When the Suspected criteria case is overwritten as 0-Not a Verified Case.

**Site of TB Disease**



**Tuberculin Skin Test and All Non-DST TB Laboratory Test Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| TestType[INV290] | SpecimenSource Site[31208-2] | Date Collected/Placed[68963-8] | Date Reported/Read[82773-3] | Test Result (Qual.)[INV291] |
| TSTTB119 | **Skin Structure****39937001** | **01/01/2019** | **01/03/2019** | **Positive****10828004** |
| IGRA-QFT LAB671 | Blood87612001 | 01/04/2019 | 01/06/2019 | Indeterminate82334004 |
| Smear20431-3 | Sputum119334006 | 01/04/2019 | 01/06/2019 | Positive10828004 |
| Culture50941-4 | **Sputum****119334006** | **01/04/2019** | **02/20/2019** | **Negative****260385009** |
| NAALAB673 | **Sputum****119334006** | **03/21/2019** |  | **Unknown****UNK** |
| NAALAB673 | **Sputum****119334006** | **03/20/2019** | **03/22/2019** | **Indeterminate****82334004** |

**Chest Radiograph or Other Chest Imaging Study Results (required results prefilled in table; unlimited number of additional results may be entered)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Study Type[LAB677] | Date of Study[LAB681] | Result[LAB678] | Cavity?[LAB679] | Miliary?[LAB680] |
| Plain Chest X-Ray | 01/04/2019 | Unknown [UNK] |  |  |
| CT Scan | **01/04/2019** | **Consistent with TB [PHC1873]** | **N** | **N** |

**Initial Drug Regimen**

|  |  |
| --- | --- |
| Drug Name [INV1143] | Used? [INV1144](Yes/No/Unknown) |
| Isoniazid | **Y** |
| Rifampin | **Y** |
| Pyrazinamide | **Y** |
| Ethambutol | **Y** |
| Streptomycin | **N** |
| Rifabutin | **N** |
| Rifapentine | **N** |
| Ethionamide | **N** |
| Amikacin | **N** |
| Kanamycin | **N** |
| Capreomycin | **N** |
| Ciprofloxacin | **N** |
| Levofloxacin | **N** |
| Ofloxacin | **N** |
| Moxifloxacin | **N** |
| Cycloserine | **N** |
| Para-Amino Salicylic Acid | **N** |
| Linezolid | **N** |
| Bedaquiline | **N** |
| Delaminid | **N** |
| Clofazimine | **N** |
| Pretomanid | **N** |
| Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **N** |



In the above example there is no Site of Disease provided so this case will fall through the criteria to 5- Suspected but since the **Case Verification Category** [**INV1115**] provided by the State is 0-Not a Verified Case it will be set to the 0-Not a Verified Case category.

**ADDITIONAL QUESTIONS**

For additional question concerning the calculation of the Case Verification Criteria, please contact DTBE Support by email (DTBESupport@cdc.gov) or by phone 1-888-300-4261.

Revisions

|  |  |  |
| --- | --- | --- |
| Date | Description | Modified By |
| 10/29/2019 | Added Not Offered option in all laboratory examples and codes | Sandy Price |
| 10/29/2019 | Added Pretomanid to all initial drug regimen examples | Sandy Price |

1. Suspected is the SNOMED CT concept name used for a Possible TB Case, a case for whom there is a high index of suspicion for active TB disease and is currently under evaluation for TB disease. [↑](#footnote-ref-1)